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DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

Dallas District
4040 North Central Expressway
Dallas, Texas 75204-3145

October 26, 2004

Ref: 2005-DAL-WL- 03

WARNING LETTER

CERTIFIED MAIL
RETURNED RECEIPT REQUESTED

Mr. Charles Jackson, CEO
Omnii Products of Palm Beach, Inc.
1500 North Florida Mango Road Suite 1
West Palm Beach, FL 33409-5208

Dear Mr. Jackson:

An inspection of your prescription drug and OTC manufacturing facility located at 12600 Exchange Drive, Stafford, Texas, was conducted on January 20 through January 23, and February 9, 2004, by an Investigator from the Food and Drug Administration (FDA). Your firm's OmniiGel 0.4% Stannous Fluoride Gel and Just for Kids Brush on Gel with 0.4% Stannous Fluoride products violate the Federal Food, Drug, and Cosmetic Act (Act), as explained below. We acknowledge your submission of revised labeling for the Just for Kids Brush on Gel dated July 8, 2004. However, the revised labeling still does not comply with the Act.

OmniiGel 0.4% stannous fluoride gel is marketed as a prescription drug by your firm. Final regulations covering OTC stannous fluoride treatment gels are found at 21 C.F.R. Part 355. Under these regulations, 0.4% stannous fluoride is to be marketed as an OTC drug. Thus, OmniiGel is not entitled to bear the "Rx only" legend because it can be marketed as an OTC drug. Therefore, the product is misbranded under Section 503(b)(4)(B) of the Act, which provides, in relevant part, that if a product may be marketed as an OTC drug, it must be marketed as such.

OmniiGel and Just for Kids Gel are also misbranded under section 502(f)(1) of the Act for failure to bear adequate directions for use, in conformance with 21 C.F.R § 355.50(d)(4). This section sets forth directions for anticaries prevention treatment drug products. The products are further misbranded under section 502(f)(2) of the Act for failure to bear the complete warning found at 21 C.F.R. § 355.50(c)(2).

OTC anticaries products are required to be labeled in the Drug Facts Format found at 21 C.F.R. § 201.66. Inasmuch as OmniiGel and Just for Kids Gel are not labeled according to this format, they are misbranded under section 502(c) of the Act. The products are further misbranded under section 502(e)(1)(A)(iii) of the Act for failure to declare their inactive ingredients. They are also misbranded under section 502(a) of the Act for failure to bear the complete labeling statements for anticaries products required by 21 C.F.R. § 355.50(e).

Because OmniiGel and Just for Kids Brush on Gel fail to comply with the final monographs as noted above, they are not generally recognized as safe and effective for their labeled indications. They are, therefore, considered "new drugs" under section 201(p) of the Act and may not be introduced or delivered for introduction into interstate commerce without an approved New Drug Application under section 505 of the Act.

The above violations are not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure that your firm's operations and controls adhere to all current regulations applicable to your operations.

These serious violations may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, seizure and/or a court injunction against further marketing of your drug products. In addition, federal agencies are advised of the issuance of all Warning Letters so that they may consider this information when awarding government contracts.

We received your letter dated April 13, 2004, which describes corrective actions taken in response to the Inspectional Observation listed on the Form FDA 483. Your corrective actions with respect to those observations that address deviations from current good manufacturing practice regulations appear to be adequate and will be verified at the next inspection. However, we have the following recommendation to a standard operating procedure (SOP) that was submitted in your response. The SOP entitled "Position Description-Chemist/Quality Control Analyst," should be revised to describe, as required by 21 C.F.R. § 211.22, the responsibility and authority of the Quality Control Unit (QCU) to approve or reject all components, drug product containers, closures, in-process materials, packaging materials, labeling and drug products, and the authority to review production records to assure that no errors have occurred or, if errors have occurred, that they have been fully investigated, and the QCU is responsible for approving or rejecting all procedures or specifications impacting on the identity, strength, quality, and purity of the drug product. When the SOP is revised, please submit a copy of this procedure with your response to the labeling issues.

Please notify this office in writing within fifteen working days from the date that you receive this letter of the actions you are taking to prevent recurrence of the violations outlined above. Your response should include the specific timeframes necessary to take these steps. Your reply should be sent to Edwin Ramos, Compliance Officer, at the above stated address. If you have any questions concerning the stated matters, you may contact Mr. Ramos at 214-253-5218.

Sincerely,

Michael A. Chappell
Dallas District Director

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